IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DEBRA ACREE, as Independent Administrator of the Estate of WILLIAM ACREE, JR., deceased,	)	
Plaintiff,	)	
vs.	)	**Case No. 10 C 7812**
WATSON PHARMACEUTICALS, INC., et al.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Debra Acree, the administrator of the estate of her late husband William Acree, has sued Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc., a Nevada corporation; Watson Laboratories, Inc., a Delaware corporation; and Watson Pharma, Inc. (collectively, Watson) for wrongful death, alleging negligence and strict product liability. Acree initially filed the case in the Circuit Court of Cook County, Illinois. Watson removed the case to federal court based on diversity of citizenship. The parties agree that Illinois law governs Acree's claims.

Watson has moved for summary judgment on three grounds: (1) Acree's claims are preempted by federal law; (2) she cannot establish the defect or causation elements required in strict product liability cases; and (3) two of the defendants, Watson Pharmaceuticals, Inc. (WPI) and Watson Laboratories, Inc., a Nevada corporation

(WLI–Nevada), are not proper parties to this case. For the reasons stated below, the Court denies Watson's motion.

Background

In its response to Acree's Local Rule 56.1 statement of material facts, Watson responds to almost every one of Acree's statements by summarily contending that the facts are "[d]isputed but irrelevant." *See generally* Defs.' Resp. to Pl.'s L.R. 56.1(b)(3) Statement of Material Facts. This general response does not comport with the requirements of Local Rule 56.1. The rule requires a party's response to the opposing party's statement of facts to contain, "in the case of any disagreement, specific references to the affidavits, parts of the record, and other supporting materials relied upon." N.D. Ill. R. 56.1(a). Watson's response contains only one citation to the record—at a spot where Watson agrees with Acree's statement that it included testimony from Dr. Prausnitz in its summary judgment brief. Although it does not affect the outcome of the motion for summary judgment, the Court finds Watson's response noncompliant with Rule 56.1. *See Ammons v. Aramark Uniform Servs., Inc.* 368 F.3d 809, 817 (7th Cir. 2004) ("[A] district court is entitled to expect strict compliance with Rule 56.1."). If the Court sees similar noncompliance by Watson with the federal or local rules in the future, it will not hesitate to impose an appropriate sanction.

Watson manufactures an FDA-approved fentanyl transdermal system patch that is the generic version of the brand-name Duragesic patch. Fentanyl is an opioid used to relieve pain. Watson's patch has five layers that in theory function as a time-release system, emitting a consistent dosage level of fentanyl over a seventy-two hour period. A consumer therefore wears each fentanyl patch for three consecutive days. The dose

of fentanyl depends on the size and type of patch and ranges from 2.5 to 10 milligrams. At the time relevant in this case, Watson sold its fentanyl patches in four strengths—25 micrograms per hour, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr. (Watson has since begun selling a 12 mcg/hr patch.) Watson's patch has a reservoir design—the patch contains a membrane which releases a fentanyl and alcohol-based gel, stored in a reservoir, directly onto the skin where it is absorbed into the body.

To obtain Food and Drug Administration (FDA) approval of its generic fentanyl patch, Watson filed an Abbreviated New Drug Application (ANDA) with the FDA, as required by federal law and FDA regulations. According to Acree, although Watson submitted its ANDA on March 31, 2003, the FDA did not give final approval for its fentanyl patch until August 20, 2007. During the interval, the FDA and Watson discussed the scientific comparison between the Duragesic fentanyl patch and Watson's generic fentanyl patch. Watson's Senior Vice-President of Research and Development, Charles Ebert, testified that while Watson's ANDA was awaiting approval, Mylan (a Watson competitor) began selling a generic-patch alternative to the Duragesic patch. Mylan's patch has a matrix design, with the fentanyl stored within a solid matrix in the patch that may or may not include a rate-controlling membrane to regulate the amount of fentanyl that the skin is absorbing.

According to Acree, WPI is the parent corporation of the other four Watson defendants. A Delaware district court recently discussed the structure of Watson as follows:

> [WPI] organizes its operations not by corporation, but by division–Generic, Brand, and Distribution. Generic Division, which is responsible for developing and submitting ANDAs, relies on contributions from Pharmaceuticals, Laboratories, and Pharma; the Generic Division's

> president is a Pharmaceuticals employee, and the Generic Division's products are manufactured by Laboratories and marketed and sold by Pharma.

Cephalon, Inc. v. Watson Pharm., Inc., 629 F. Supp. 2d 338, 343 (D. Del. 2009).

Ebert testified that while acting as Senior Vice-President of Research and Development at WPI, he oversaw the design phase of the Watson fentanyl patches. WPI's website describes the corporation as a "global pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, brand and biologic pharmaceutical products." Pl.'s Ex. BB. Watson employee Stephen Kaufhold testified that WLI–Nevada pays for all of the raw materials that are used to manufacture Watson's fentanyl patch. It is undisputed that WLI–Nevada submitted the ANDA for the Watson fentanyl patch. Watson disputes, however, WPI's role in the development of the fentanyl patch, claiming that WPI is merely a holding company.

William Acree (Mr. Acree) began wearing fentanyl patches in May 2005, due to chronic back pain that he suffered as the result of an automobile accident in 2001. Dr. Srinivas Sunkavally, Mr. Acree's doctor, prescribed him 125 mcg/hr of fentanyl, which required Mr. Acree to wear one 100 mcg/hr patch and one 25 mcg/hr patch simultaneously. Acree testified that she helped apply these patches to Mr. Acree's arm every three days. Acree contends that the 125 mcg/hr dose of fentanyl should have given Mr. Acree a fentanyl concentration of 3.1 ng/ml in his bloodstream.

According to Acree, she applied two new fentanyl patches on Mr. Acree's arm on the morning of January 19, 2009. Mr. Acree went to bed that evening around 7:30 p.m. and was not awake when Acree left for work around 4 a.m. the next morning. Acree called home around 9:40 a.m., during her break, and her son, William Daniel Acree

(Daniel), told her that he would awaken his father. Daniel testified that when he approached Mr. Acree, he was pale and his eyes were open. Daniel called 911, and paramedics tried to resuscitate Mr. Acree, removing his fentanyl patches at some point in the process. The paramedics transported him to a nearby hospital, where he was pronounced dead. The fentanyl patches were not recovered.

Dr. J. Scott Denton, a forensic pathologist, performed an autopsy on Mr. Acree. Denton concluded that Mr. Acree's death was caused by "fentanyl intoxication," and his report listed a concentration of 23.6 ng/ml of fentanyl in Mr. Acree's bloodstream. Defs.' Ex. D at 5. Denton testified that the elevated level of fentanyl, together with the circumstances surrounding Mr. Acree's death—which Denton concluded were "classic kind[s] of opiate or drug intoxication symptoms"—led him to conclude that fentanyl intoxication caused the death. Pl.'s Ex. I at 33.

Watson disputes that the coroner's report accurately documents the level of fentanyl in Mr. Acree's blood at the time of his death. It contends the 23.6 ng/ml level is artificially high, due to a process called "postmortem redistribution," where drugs redistribute throughout the body after death, resulting in different concentrations in the central blood than in the peripheral blood. Watson has submitted an affidavit from Dr. Christopher Milroy, a forensic pathologist, who opined that postmortem concentrations of fentanyl cannot provide any reliable information about the level of fentanyl present before death. Milroy also questioned Mr. Acree's cause of death, citing a number of other health problems Mr. Acree suffered from that may have caused or contributed to his death, including a history of heart problems, asthma, and gout.

Acree has submitted expert testimony from Dr. J.C. Upshaw Downs, a forensic pathologist, who opined that but for the level of fentanyl in Mr. Acree's system, he would not have died when he did. Downs agreed that postmortem redistribution should be considered as a possible factor when assessing a cause of death, and he acknowledged that pre-mortem drug concentrations cannot be measured. Downs reported, however, that people with lower concentrations of fentanyl have died from fentanyl toxicity, and he stated that even if postmortem redistribution occurred, that would not change his opinion that fentanyl intoxication caused Mr. Acree's death.

Acree has also submitted expert testimony from Dr. Mark R. Prausnitz, a chemical and biomedical engineering professor, who opined that the level of fentanyl found in Mr. Acree's blood was "more likely than not, and most probably," the result of a leak or defect in the Watson fentanyl patches. Pl.'s Ex. D at 24. Prausnitz stated that the matrix-design fentanyl patch is a superior design to the reservoir-design fentanyl patch. Prausnitz also opined that as early as 2004, information about the occurrence of leaks in the reservoir-design patches was publicly available.

Discussion

Summary judgment is appropriate when the evidence demonstrates that there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 898 (7th Cir. 2011). In deciding on a motion for summary judgment, courts "view the record in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor." *Groesch v. City of Springfield*, 635 F.3d 1020, 1022 (7th Cir. 2011). "It is not for courts at summary judgment to weigh evidence or

determine the credibility of such testimony." *Berry v. Chicago Transit Auth.*, 618 F.3d 688, 691 (7th Cir. 2010) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)).

Watson initially moved for summary judgment on six grounds. In response to the motion, however, Acree agreed to dismiss several of her claims against Watson, pursuing only her claims for negligence and strict liability on the basis of design defect and manufacturing defect. Thus, only three issues raised by Watson in its motion remain relevant: (1) whether Acree's claims are preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*; (2) whether Acree has presented evidence on the issues of defect and causation sufficient to survive summary judgment; and (3) whether WPI and WLI–Nevada should be dismissed as defendants.

As an initial matter, Watson has presented two statements from emergency personnel who responded to Daniel's 911 call, stating that they did not observe any rips, tears, or holes in the patches they took off of Mr. Acree on January 20, 2009, nor did they see any gel or gel residue on Mr. Acree's skin. These declarations were presented by Watson for the first time on reply. As a result, Acree had no opportunity to address the statements. The Court makes no ruling regarding whether this evidence will be admissible at trial, but it will not consider these statements for purposes of summary judgment. *See, e.g., Mathis v. Fairman*, 120 F.3d 88, 91 (7th Cir. 1997); *Elizarri v. Sheriff of Cook Cnty.*, No. 07 C 2427, 2011 WL 247288, at *3 (N.D. Ill. Jan. 24, 2011).

II. Preemption

The Constitution's Supremacy Clause provides that federal law "shall be the supreme Law of the Land . . . and any Thing in the Constitution or Laws of any State to

the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Pursuant to the Supremacy Clause, "[w]here state and federal law directly conflict, state law must give way." *PLVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567, 2577 (2011) (internal quotation marks omitted). State and federal law conflict when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

In *PLIVA*, the Supreme Court found that two plaintiffs' state-law claims against generic drug manufacturers for failing to provide adequate warning labels were preempted by the FDCA. *PLIVA*, 131 S. Ct. at 2573. The Court explained that because the FDCA requires a generic drug manufacturer to have the same warning label as the brand-name drug, it is impossible for generic drug manufacturers to "independently do under federal law what state law requires of [them]"—namely, label their products adequately and safely in a way required by state law. *Id.* at 2579. Even though the FDCA requires generic drug manufacturers to ask the FDA for help in strengthening the brand-name drug's label, the Court held that the generic manufacturers themselves could not independently change the label to differ from that on the brand-name drug. *Id.* at 2580–81. Watson argues that the rationale supporting *PLIVA* applies with equal force to Acree's design-defect claims because the FDCA similarly prohibits generic drug manufacturers from changing the design of their drug product.

The First Circuit, in *Bartlett v. Mutual Pharmaceutical Co.*, 678 F.3d 30 (1st Cir. 2012), has noted that: "Whether and to what extent the FDCA preempts design defect claims against generic drug manufacturers is a question of exceptional importance that

the Supreme Court has yet to decide." *Bartlett*, 678 F.3d at 36. Lower courts have split on the issue, and there is no Seventh Circuit law directly on point.

The court in *Bartlett* found that it was not impossible for the generic drug manufacturer to comply with both federal and state law regarding its drug design because the manufacturer could "choose not to make the drug at all." *Id.* at 37. *But see In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-MD-2226, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012) (considering the failure-to-withdraw argument "an oversimplified solution that could apply anytime the issue of impossibility preemption arises"). The Court need not address the failure-to-withdraw issue, however, because the unique circumstances of this case are such that Watson could have complied with both the FDCA and the particular state-law duty that Acree alleges Watson violated.

The Court begins with a discussion of what state law requires. Illinois courts have held that to prevail on a strict product liability claim, a plaintiff must show "that the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control." *Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 525, 901 N.E.2d 329, 335 (2008). When pursuing a strict liability claim on the basis of an alleged design defect, "a plaintiff may demonstrate that a product is unreasonably dangerous because of a design defect by presenting evidence of an alternative design that would have prevented the injury and was feasible in terms of cost, practicality and technological possibility." *Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420, 436, 764 N.E.2d 35, 45 (2002). Acree contends that the matrix-type fentanyl patch design was feasible and a

safer alternative design to the reservoir patch, and that Watson therefore violated its state-law duty by manufacturing and selling the reservoir patch.

One court in this district has held that design-defect claims are not preempted by the FDCA because the liability resulting from a design defect is not based on any affirmative duty imposed by the state. *Halperin v. Merck, Sharpe & Dohme Corp.*, No. 11 C 9076, 2012 WL 1204728, at *3 (N.D. Ill. Apr. 10, 2012) ("[S]trict liability based on a design defect generally applies to all entities in the chain of commerce . . . regardless of culpability, duty, knowledge, or fault."). Yet even if design-defect liability does impose an affirmative duty on those involved in the stream of commerce, the unique circumstances of the present case save Acree's claims from preemption.

The FDCA requires a drug manufacturer to submit an ANDA for FDA approval before it can market and sell a generic drug. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94. The ANDA process allows drug manufacturers to develop generic drugs inexpensively, "without duplicating the clinical trials already performed on the equivalent brand-name drug." *PLIVA*, 131 S. Ct. at 2574. The ANDA must document, among other things, that the generic drug has the same conditions of use, active ingredient(s), and route of administration as the brand name drug and that the two drugs are bioequivalent—specifically, that the generic drug delivers the active ingredient to the body at the same rate and to the same extent as the brand name drug. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. §§ 314.94(a) (describing the required content of an ANDA), 320.1(e) (defining bioequivalency). A drug manufacturer may amend its ANDA prior to FDA approval to "revise existing information or provide additional information." 21 C.F.R. § 314.96.

Watson's generic fentanyl patch was modeled on the brand-name Duragesic patch, which used a reservoir design. Watson contends that for this reason, the FDA would not have approved Watson's ANDA if it used the matrix-type design. Yet the testimony from Watson's own employee, Charles Ebert, directly contradicts Watson's position. He testified during his deposition that the FDA approved another manufacturer's matrix-type fentanyl patch as an appropriate generic equivalent for the Duragesic patch in January 2005. Ebert also testified that at that point, Watson knew that the FDA would approve an ANDA for a matrix-type generic fentanyl patch. Watson's own ANDA was not finally approved until more than two years later, in August 2007. Thus Watson could have amended its ANDA to include a matrix design, without having to seek separate FDA approval beyond what was already required for its then-pending ANDA. In fact, Watson did amend its ANDA in January 2006 to include an additional bioequivalence study and again in June 2006 to include a summary of its two previously submitted studies. Ex. B at 21625–30. Thus, though it may have been time-consuming and expensive for Watson to change the design of its fentanyl patch, it was not impossible for Watson to change its design to a matrix-type design prior to FDA approval. As a result, it was not impossible for Watson to comply with both the FDCA and the state-law requirements upon which Acree relies. *See Wyeth v. Levine*, 555 U.S. 555, 573 (2009) ("Impossibility pre-emption is a demanding defense."). Acree's design-defect claims are therefore not preempted by federal law.

III. Defect and causation

Watson next contends that Acree has not provided sufficient evidence on the issues of defect and causation to survive summary judgment. Watson argues that

Acree has no direct evidence to prove that the patches were defective and caused Mr. Acree's death and that her circumstantial evidence is merely speculative and does not give rise to a genuine issue of material fact.

As indicated above, to prevail on her strict product liability claims, Acree must show "that the injury complained of resulted from a condition of the product, that the condition was an unreasonably dangerous one, and that the condition existed at the time the product left the manufacturer's control." *Kelso v. Bayer Corp.*, 398 F.3d 640, 642 (7th Cir. 2005) (citing *Sollami v. Eaton*, 201 Ill. 2d 1, 7, 772 N.E.2d 215, 219 (2002)). Additionally, to succeed on her claim of negligence, Acree must prove "that the construction or design of the [product] breached a duty of care and was the proximate cause of [her] injury." *Malen v. MTD Prods., Inc.*, 628 F.3d 296, 303 (7th Cir. 2010); *see also Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247, 270, 864 N.E.2d 249, 263 (2007). Watson correctly notes that proof of defect and causation is essential to all of Acree's claims. *See Malen*, 628 F.3d at 303; *Pearson v. Telsmith, Inc.*, No. 92 C 3250, 1996 WL 495571, at *2 (N.D. Ill. Aug. 28, 1996) ("The standard for proof of causation is the same in a strict product liability case as it is in negligence.") (citing *Smith v. Eli Lilly & Co.*, 137 Ill. 2d 222, 232–33, 560 N.E.2d 324, 328 (1990)).

As noted earlier, the patches that Mr. Acree was wearing are long since gone. Watson contends that because Acree cannot point to any specific defect in the actual patches that were used, she must show that but for a defect in the patches, Mr. Acree would not have died. To the contrary, "Illinois courts have acknowledged that the unavailability of the product does not preclude a plaintiff from proving that a product was defective through circumstantial evidence." *DiCosolo v. Janssen Pharm., Inc.*, ___ Ill.

App. 3d ___, 951 N.E.2d 1238, 1244 (2011). Illinois courts allow a plaintiff to create an inference of a product's defect through direct or circumstantial evidence that: (1) there was no abnormal use of the product; (2) there was no reasonable secondary cause of the injury; and (3) the product failed to perform in the manner reasonably to be expected in light of its nature and intended function. *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 574, 357 N.E.2d 449, 452 (1976); *Doyle v. White Metal Rolling & Stamping Corp.*, 249 Ill. App. 3d 370, 377, 618 N.E.2d 909, 916 (1993); *see also Weedon v. Pfizer, Inc.*, 332 Ill. App. 3d 17, 22, 773 N.E.2d 720, 724 (2002) ("[A] plaintiff may establish a nonspecific defect claim by circumstantial evidence.").

Because Acree cannot directly prove that the fentanyl patches Mr. Acree was wearing at the time of his death malfunctioned, she relies on circumstantial evidence to show that Watson's patches were defective and that the defect caused Mr. Acree's death. The patches Mr. Acree wore were designed to deliver approximately 3.1 ng/ml of fentanyl into his system. His autopsy, however, revealed a postmortem concentration of 23.6 ng/ml of fentanyl. The coroner's report lists the cause of death as fentanyl intoxication, and the forensic pathologist who performed Mr. Acree's autopsy testified that circumstances surrounding Mr. Acree's death suggested fentanyl intoxication as the cause of death. Acree has presented additional testimony from two other experts. As indicated earlier, Downs testified that Mr. Acree's death was the direct result of "acute fentanyl toxicity." Pl.'s Ex. K at 3. Prausnitz further testified that the high level of fentanyl found in Mr. Acree's blood was "most probably the result of a leak or other defect" in the Watson patches. Pl.'s Ex. D at 23. Finally, Acree has presented evidence from present and former Watson employees, who testified that there have been other

occurrences of reservoir patches that improperly leaked fentanyl gel. Acree contends that this evidence, taken together, is sufficient to permit a reasonable jury to find that the Watson patches that Mr. Acree was wearing on January 20, 2009 were defective and that the defect caused his death.

Causation cannot be based on "mere speculation, guess, or conjecture"; a plaintiff must present evidence sufficient to "justify a reasonable inference of probability of negligence, as distinguished from mere possibility." *Gyllin v. Coll. Craft Enters., Ltd.*, 260 Ill. App. 3d 707, 714, 633 N.E.2d 111, 117 (1993); *see also Show v. Ford Motor Co.*, 697 F. Supp. 2d 975, 984 (N.D. Ill. 2010) (applying Illinois law). Yet circumstantial evidence will satisfy this requirement if "it tends to negate other reasonable causes." *Varady v. Guardian Co.*, 153 Ill. App. 3d 1062, 1067, 506 N.E.2d 708, 711 (1987); *see also Weedon*, 332 Ill. App. 3d at 29, 773 N.E.2d at 730 ("The plaintiff is not required to prove his claim at the summary judgment stage, but must present some facts to support his claim."). Nearly forty years ago, the Seventh Circuit explained the difference between purely speculative evidence and reasonably reliable circumstantial evidence:

> Circumstantial evidence may contradict and overcome direct and positive testimony. The limitation on its use is that the inference drawn must be reasonable. But there is no requirement that the circumstances, to justify the inferences sought, negative every other positive or possible conclusion. The law is not so exacting that it requires proof of negligence or causation by testimony so clear that it excludes every other speculative theory.

Musgrave v. Union Carbide Corp., 493 F.2d 224, 228 (7th Cir. 1974). Viewing the evidence in the light most favorable to Acree, the Court finds that she has presented sufficient circumstantial evidence to permit an "inference of probability" that the Watson patches were defective and caused Mr. Acree's death. Watson's evidence about

"postmortem redistribution" may make Acree's evidence less persuasive to a jury, but it does not prevent her from surviving summary judgment. The issues of defect and causation thus involve genuine factual disputes that must be resolved by a jury.

IV. WPI and WLI–Nevada as defendants

Watson's final argument is that WPI and WLI–Nevada should be dismissed as defendants because they did not manufacture, distribute, or sell the Watson fentanyl patches. Under Illinois law, "all entities in the distributive chain of an allegedly defective product, including manufacturers, sellers, wholesalers, distributors and lessors of the product, are strictly liable in product liability actions for injuries resulting from that product." *Murphy v. Mancari's Chrysler Plymouth, Inc.*, 381 Ill. App. 3d 768, 772–73, 887 N.E.2d 569, 574 (2008) (citing *Kellerman v. Crowe*, 119 Ill. 2d 111, 113, 518 N.E.2d 116, 117 (1987)). In a negligence claim, by contrast, "fault is an issue, because the inability of a defendant to know of or prevent the risk could preclude a negligence finding." *Murphy*, 381 Ill. App. 3d at 773, 887 N.E.2d at 575 (citing *Townsend v. Sears, Roebuck & Co.*, 227 Ill. 2d 147, 156, 879 N.E.2d 893, 899 (2007)).

Viewing the evidence in the light most favorable to Acree, the Court concludes that there are genuine issues of material fact regarding WPI and WLI–Nevada's role in the production, manufacture, and sale of the Watson fentanyl patches that preclude entry of summary judgment in their favor. Ebert, who from at least 2006 to 2011 was the Senior Vice President of Research and Development at WPI, testified that he oversaw the design phase of the Watson fentanyl patches, including the actual design of the product and the manufacture of the materials for testing. A page on WPI's website lists the entity as a "global pharmaceutical company engaged in the

development, manufacturing, marketing, sale and distribution of generic, brand and biologic pharmaceutical products." Pl.'s Ex. BB. This evidence tends to undercut Watson's contention that WPI is merely a holding company. As to WLI–Nevada, Kaufhold testified that WLI–Nevada pays for all of the raw materials that are used to manufacture Watson's fentanyl patch. Additionally, WLI–Nevada submitted the ANDA for the Watson fentanyl patch, and it communicated with the FDA throughout the approval process.

For these reasons, the Court declines to grant summary judgment in favor of WPI and WLI–Nevada.

Conclusion

For the reasons stated above, the Court denies Watson's motion for summary judgment [docket no. 75].

MATTHEW F. KENNELLY
United States District Judge

Date: October 26, 2012